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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,758	10/17/2003	Michael T.K. Ling	FLM-5686A	1992
7590 MARK J. BUONAIUTO, ESQ. ASSISTANT GENERAL COUNSEL BAXTER INTERNATIONAL INC., LAW DEPARTMENT ONE BAXTER PARKWAY, DF3-2E DEERFIELD, IL 60015			EXAMINER HAIDER, SAIRA BANO	
			ART UNIT 1711	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/688,758	LING ET AL.
	Examiner Saira Haider	Art Unit 1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 November 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-13,15,16,18-20,22,24-26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-13,15,16,18-20,22,24-26 and 28-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - a. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 20, 22, 24-26, and 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term “outermost” has been recited in the claims to somehow limit the structure of the layers.
3. It is noted that the 35 U.S.C. 112, first paragraph rejection of claims 1, 2, 4-13, 15-16, 18-19 has been withdrawn. Applicants have directed attention towards Figures 2 and 3 as providing support for the term “outermost.” The examiner agrees that Figures 2 and 3 provide support for the term “outermost,” only when the term refers to the first layer. Hence sufficient support is present for the phrase “outermost first layer.” However, the Figures fail to provide support for the term “outermost” when followed by the phrase “second layer.” The figures do not show an instance wherein the second layer is the outermost layer. Hence the new matter rejection has been withdrawn for those claims with the phrase “outermost first layer,” and the rejection has been maintained for those claims with the phrase “outermost second layer.”

4. Although the specification provides support for an "outer" layer, it does not appear to support an "outermost" layer. The two terms outer and outermost can be considered to describe distinct positions in the layering structure, for example the term "outer" can encompass more than one layers which are situated father out from the core layer. On the other hand, the term "outermost" is considered to describe a layer which is the farthest out from the core, and does not have any subsequent layers which are farther out from the core layer. The relationship between the term outer and outermost is analogous to the genus and species relationship. Wherein disclosure of the genus does not provide support for all species contained thereof. Hence, disclosure of outer does not provide support for outermost.

5. Claims 1-2, 4-13, 15-16, 18-20, 22, 24-26, and 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "solution contact" has been recited in the claims to somehow limit type of contact between the layers, it appears that applicant's specification does not provide support or guidance as to the requirement(s) for this type of contact.

6. Applicants have argued that the term "solution contact" is supported in the specification. In support of this argument applicants have cited *In re Wertheim* and *Eiselstein v. Frank*. Applicants have essentially argued that it is not necessary that the patent application describe the claimed subject matter in exactly the same terms as used in the claims, and that one of ordinary skill would recognize that the inventor had possession of the claimed subject matter at the time of the

invention. The examiner has thoroughly considered applicants' arguments and the presented case law and maintains the new matter rejection.

7. Firstly, regarding utilization of exactly the same terms in the patent application as in the claims, the examiner agrees that exact terms need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112, however, 37 CFR 1.121(e) requires *substantial* correspondence between the language of the claims and the language of the specification. Neither the applicants nor the examiner have identified portions in applicant's specification where there is a term which substantially corresponds to a "solution contact" layer.

8. Secondly, a review of the cited US Patent No. 6,974,447 reveals that the term "solution contact layer" is utilized to identify a layer of a port tube which is contacted with a solution. Hence, one skilled in the art of port tubes would understand "a solution contact layer" to be a layer which is or can be in contact with a solution. Applicant's specification however does not convey this understanding, as evidenced by the specification and Figures 1-3. Applicants' "solution contact" layer appears to be a layer adjacent to two other polymeric layers and does not appear to have contact with any solution. Additionally, applicant's claims are not drawn to port tubes, and hence the term "solution contact layer" to one skilled in the art of the claimed tubing structures would not necessarily imply the same definition as utilized in the port tubing art. Hence the new matter rejection is maintained.

9. In the prior art rejections, the examiner has given the broadest reasonable interpretation to the term "solution contact" layer. In the absence of guidance from applicants' specification and the understanding of one skilled in the art, the examiner has constructed the term "solution contact" to refer to a process limitation.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

b. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-2, 4-13, 15-16, 18-20, 22, 24-26, and 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "solution contact" renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisites, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1-2, 4-13, 15-16, 18-19, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. in view of Laurin et al.

14. Woo discloses a multi-layered non-PVC containing tubing structure comprising an outer layer, a tie layer, and an inner layer (abstract). The outer layer can comprise 40-99% by weight of a polypropylene copolymer having 2-6% polyethylene and 1-60% by weight of a styrene-ethylene-butylene-styrene (SEBS) thermoplastic elastomer copolymer (col. 3 lines 10-17). Hence Woo discloses two [(a) and (d)] of the four components [(a)-(d)] of the outermost first layer.

15. In reference to the limitation regarding an outermost first layer, it is noted as per Figure 1 in Woo, that the outer layer is the outermost layer since the tubing structure of Woo does not have any subsequent layers which are farther out from the core layer.

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16. A second layer, the tie layer, comprises 30-60% by weight of a Hytrel copolyester, 0-20% by weight of a polypropylene copolymer having 2-6% polyethylene, 30-60% by weight of a SEBS thermoplastic elastomer, and 0-30% by weight of ethylene-vinyl acetate (col. 3 lines 38-49). Note that the applicant recognizes the exemplified copolyester, Hytrel 4056, as a polyester polyether block copolymer and recognizes the exemplified ethylene-vinyl acetate, UE 697, as a suitable material having the claimed vinyl acetate content. In this sense, the second layer is coaxially mounted within the first layer, and meets the newly added limitation of the second layer contacting the first layer.

17. In reference to the newly added limitation regarding a solution contact second layer, it is the examiner's position that the term "solution contact" is a process limitation, hence would not materially differentiate the claimed layer from the layer of the prior art.

18. Regarding claim 34, it is noted that the second layers are bonded to a second tubing (figures). It is the examiner's position that the process for bonding the tubing would not materially differentiate the claimed tubing from the tubing of the prior art (product-by-process claim). Therefore, the prior art teaches this bonded layer.

19. Regarding claim 35, Woo teaches that the tubing is attached to containers made from flowable materials; thus, the reference teaches that the first layer is attached to a flowable material container (col. 4 lines 29-40).

20. In reference to claim 1, Woo applies as above, teaching multi-layered tubing structures having blended components [components (a) and (d)] but failing to mention the claimed second polyolefin polymer or RF susceptible polymer of layer 1 [components (b) and (c)]. Hence attention is directed toward the Laurin reference. Laurin teaches similar blend compositions, where polypropylene polymers are blended with a second polyolefin (b), a dimer fatty acid polyamide or other RF susceptible polymer (c), and a compatibilizing block copolymer thermoplastic elastomer

(col. 4 lines 1-23). The examples demonstrate the claimed amounts of components. The second polyolefin serves to confer flexibility and low temperature ductility to the blend, and the RF polymer imparts RF dielectric loss. Thus, in the first layer of the Woo reference, it would have been *prima facie* obvious to combine components (b) and (c) as disclosed by Laurin with components (a) and (d) as disclosed by Woo to improve flexibility, low temperature ductility, and RF dielectric loss.

21. Woo does not disclose the claimed functionalized block copolymers of claims 10-13. Hence attention is directed toward the Laurin reference. Laurin teaches similar blend compositions, where polypropylene polymers are blended with a second polyolefin, a dimer fatty acid polyamide or other RF susceptible polymer, and a compatibilizing block copolymer thermoplastic elastomer (col. 4 lines 1-23). The examples demonstrate the claimed amounts of components. SEBS copolymers are preferably functionalized with maleic anhydride or other polar monomers to enhance the compatibility with polar polymers (col. 7 lines 37-50). Thus, it would have been *prima facie* obvious to use maleic anhydride-modified SEBS polymers in the Woo invention to enhance the compatibility of non-polar polymers with polar polymers.

22. Regarding the second layer, Woo applies as above, failing to teach the combination of a thermoplastic elastomer and a copolymer selected from the claimed Markush group. Laurin teaches blends of polyolefins and polar polymers, where both SEBS and functionalized SEBS materials are used as a compatibilizer for the polar and non-polar components (col. 7 lines 38-58). It is the examiner's position that it would have been *prima facie* obvious to include both the SEBS and functionalized SEBS components in the second layer, blended tie layer, of Woo in any amounts sufficient to optimize the compatibility of the polar and non-polar components.

23. Claims 20, 22, 24-26, 28-33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. in view of Laurin et al., and further in view of Strassmann.

24. Woo and Laurin apply as above, teaching multi-layered tubing structure for tubing ports, but failing to teach the newly added limitations regarding the outermost second layer. They also fail to teach, as per claim 22, that the first blend layer is coaxially mounted within the second blend layer. Strassmann teaches tubing port structures, where the bag is mounted coaxially onto the outside of the tubing (figures). The bags are made of the same blend materials as the outer layers of the tubing to optimize adhesion (examples). It would have been *prima facie* obvious to use bags of blended materials and mount the bags onto the outer layer of the tubing to provide conventional bag structures having optimized adhesion to the tubing.

25. Specifically, it would have been obvious to have the outermost layer of the tubing and the innermost layer of the bag be the taught blended tie layer (second layer), since this layer is known to contain polar and nonpolar groups which exhibit excellent bonding properties to adjacent layers. It is clear that when the outermost layer of the tubing is the blended tie layer then the first layer is coaxially mounted therein, since, as per the disclosure of Woo, the tie layer and first layer are coaxial to each other and possess strong adhesion (Woo col. 3, lines 38-51).

26. In reference to the newly added limitation regarding a solution contact first layer, it is the examiner's position that the term "solution contact" is a process limitation, hence would not materially differentiate the claimed layer from the layer of the prior art.

27. Regarding claim 36, which states that the second layer is solvent bonded to a second tubing, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to apply to the exterior of the taught tubing structure duplicate tubing. The motivation to do so would have been to further improve flexibility, low temperature ductility, and

RF dielectric loss. It has been held that duplication of parts is *prima facie* obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

28. Regarding claim 37, it is the examiner's position that the claim as constructed does not require the entire outermost tubing structure to be comprised of a seamless second layer, hence there exist minor portions wherein the first layer is the outermost. Subsequently, upon adhering of the tubing port to the flexible bag, the first layer is attached to the flowable material container.

Response to Arguments

29. Applicants have essentially argued that Woo and Laurin, either alone or in combination, fail to teach or suggest a multiple layer non-PVC tubing having a four-component outermost layer in contact with a solution contact layer. In support of this argument, applicants have stated that Woo only discloses two of the four claimed components. The examiner has recognized that Woo this fact, and has provided the Laurin reference to teach in the remaining two components. Additionally, applicants have stated that Woo discloses an outer layer, a tie layer, and a core layer, instead of the claimed outermost first layer and solution contact second layer. The examiner has thoroughly considered the arguments and the references, and concludes that in the absence of guidance from applicants' specification and the understanding of one skilled in the art regarding the meaning of a "solution contact", the examiner has given the term the broadest reasonable interpretation and construed the term "solution contact" to refer to a process limitation.

30. Applicants have argued that Laurin fails to fulfill the deficiencies of Woo, in support of this argument applicants have stated that Laurin is directed to 3- and 4- component polymeric blends, not multiple layer tubing. Basically, applicants are arguing that Laurin is nonanalogous art, however, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if

not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Laurin is considered to be analogous art because it is in applicant's field of endeavor, formation of 4-component polymeric blends. One of ordinary skill in the art would readily look towards the Laurin reference to improve the 2-component polymeric blend comprising the first layer of Woo. It is not necessary that Laurin disclose multiple layer tubing, the Laurin reference has been relied upon by the examiner to teach in two additional components in the first layer polymeric blend of Woo.

31. Applicants have argued that no combination of Woo, Laurin and/or Strassman discloses or suggests a multiplayer later tubing having an outermost layer that contains the claimed polyester polyether block copolymer. It is noted that Woo discloses that the claimed polyester polyether block copolymer is present in the second layer, the examiner has relied upon the Laurin reference to teach the combination of a thermoplastic elastomer and a copolymer selected from the claimed Markush group. Lastly, the examiner has relied upon the Strassman reference to teach that the second layer taught by the combination of Woo and Laurin can be utilized as an outermost layer in multiple layer tubing. In each *prima facie* case of obviousness, the examiner has provided sufficient rational and motivation for the combination or modification. Applicants have not specifically pointed out how the language of the claims patentably distinguishes them from the references.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

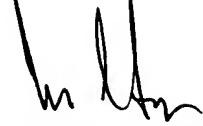
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Haider whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Saira Haider
Examiner
Art Unit 1711



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